

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC. and
CORDIS CORPORATION,

Defendants.

Civil Action No. 07-333-SLR

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC. and
CORDIS CORPORATION,

Defendants.

Civil Action No. 07-348-SLR

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC. and
CORDIS CORPORATION,

Defendants.

Civil Action No. 07-409-SLR

**PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTIONS
TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

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TABLE OF CONTENTS

	Page
NATURE AND STAGE OF THE PROCEEDINGS	1
INTRODUCTION	2
STATEMENT OF RELEVANT FACTS	4
ARGUMENT	6
I. BSC Satisfies the Proper Legal Standard for Declaratory Judgment Jurisdiction	6
A. Cordis Applies an Overly-Narrow “Test” for Standing	6
B. BSC’s Complaints Fully Satisfy the Proper Test for Standing	8
C. The Northern District of California Recently Found that BSC Had Standing in a Case With the Same Relevant Facts	10
II. BSC’s Complaints Also Satisfy Cordis’s Overly-Narrow “Test” for Standing	11
A. Cordis Has Accused the Same Stent that Abbott Makes for BSC of Infringing the Cordis Patents at Issue in BSC’s Complaints	11
B. BSC Has the Immediate Intention of Selling the PROMUS Stent in the U.S.	12
III. This Court Should Not “Decline to Hear the Case,” as Cordis Urges; Rather, this Court Should Hear this Case and Abbott’s Related Cases Together	15
CONCLUSION	16

TABLE OF AUTHORITIES**Pages****Statutes**

28 U.S.C. § 2201(a)	6
35 U.S.C. § 271(b)	3, 11
35 U.S.C. § 271(e)(1)	14

Cases

<i>Abbott Diabetes Care, Inc. v. Dexcom, Inc.</i> , No. 05-590, 2006 WL 2375035 (D. Del. Aug. 16, 2006)	13, 14
<i>Abbott Labs. v. Baxter Healthcare Corp.</i> , No. 04-C-836, 2004 WL 1878291 (N.D. Ill. Aug. 16, 2004)	14
<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967)	8
<i>Abbott Labs. v. Zenith Labs., Inc.</i> , 934 F. Supp. 925 (N.D. Ill. 1995)	13, 14
<i>Allen v. Wright</i> , 468 U.S. 737 (1984)	7
<i>AlphaMed Pharm. Corp. v. Arriva Pharm., Inc.</i> , 391 F. Supp. 2d 1148 (S.D. Fla. 2005)	13, 14
<i>Amgen, Inc. v. Hoechst Marion Roussel, Inc.</i> , 3 F. Supp. 2d 104 (D. Mass. 1998)	13, 14
<i>Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.</i> , 846 F.2d 731 (Fed. Cir. 1988)	12
<i>EMC Corp. v. Norand Corp.</i> , 89 F.3d 807 (Fed. Cir. 1996)	15
<i>Fina Research, S.A. v. Baroid Ltd.</i> , 141 F.3d 1479 (Fed. Cir. 1998)	11, 12
<i>Glaxo, Inc. v. Novopharm, Ltd.</i> , 110 F.3d 1562 (Fed. Cir. 1997)	15
<i>Glaxo Group Ltd. v. Apotex, Inc.</i> , 130 F. Supp. 2d 1006 (N.D. Ill. 2001)	14
<i>Lang v. Pacific Marine & Supply Co., Ltd.</i> , 895 F.2d 761 (Fed. Cir. 1990)	13
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992)	8
<i>Md. Cas. Co. v. Pac Coal & Oil Co.</i> , 312 U.S. 270 (1941)	6, 7

<i>MedImmune, Inc. v. Genentech, Inc.</i> , 127 S. Ct. 764 (2007)	<i>passim</i>
<i>Minn. Mining & Mfg. v. Chemque, Inc.</i> , 303 F.3d 1294 (Fed. Cir. 2002)	11
<i>Sandisk Corp. v. STMicroelectronics, Inc.</i> , 480 F.3d 1372 (Fed. Cir. 2007)	7, 9, 10
<i>Telectronics Pacing Sys., Inc. v. Ventrex, Inc.</i> , 982 F.2d 1520 (Fed. Cir. 1992).....	13, 14
<i>Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.</i> , 482 F.3d 1330 (Fed. Cir. 2007).....	7, 8, 10

NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively “BSC”) respectfully submit this answering brief in opposition to Defendants Johnson & Johnson, Inc. and Cordis Corp.’s (collectively “Cordis”) two motions to dismiss all three of BSC’s pending declaratory judgment complaints against Cordis. BSC’s three complaints seek declarations, respectively, that Cordis’s U.S. Patent Nos. 7,217,286 (the “Falotico ’286 patent”), 7,223,286 (the “Wright ’286 patent”) and 7,229,473 (“the Wright ’473 patent,” and collectively, the “Cordis patents”) are invalid or not infringed by BSC’s PROMUS everolimus-eluting stent.

On July 18, 2007, Cordis filed its first motion to dismiss BSC’s C.A. Nos. 07-333-SLR (directed to the Falotico ’286 patent) and 07-348-SLR (directed to the Wright ’286 patent), with a single memorandum in support of its request to dismiss both actions. (C.A. No. 07-333, D.I. 10, 11; C.A. No. 07-348, D.I. 8, 9; “Opening Brief”). Later, on July 26, 2007, Cordis filed its second motion to dismiss BSC’s C.A. No. 07-409-SLR (directed to the Wright ’473 patent), without any memorandum in support. (C.A. No. 07-409, D.I. 7).¹ Instead, in its second motion to dismiss, Cordis incorporated by reference its first memorandum of July 18 and stated that “[t]he basis for the requested relief already is full set forth” therein. (*Id.* at 1). Therefore, the parties stipulated, and the Court ordered, that BSC can file this single paper in opposition to both of Cordis’s motions to dismiss.

¹ Abbott has filed its own declaratory judgment action in this Court against each of these three Cordis patents, likewise seeking a declaration that those patents are invalid or not infringed by Abbott’s XIENCE V stent. Cordis is seeking to dismiss Abbott’s complaint and/or transfer it to the District of New Jersey. BSC believes that all of the issues surrounding the Cordis patents and the XIENCE V and PROMUS stents should be resolved here, in this Court. If the Court believes that it would be more efficient, BSC is amenable to consolidation of its declaratory judgment complaints with Abbott’s.

INTRODUCTION

This Court has jurisdiction over BSC's complaints because, under the Supreme Court's recently-enunciated standard, they set forth a "substantial controversy, between parties [BSC and Cordis] having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). Indeed, in a pending case in the Northern District of California where Abbott is a defendant and the XIENCE V everolimus-eluting stent is at issue, the court recently found that BSC met the *MedImmune* test for standing based on the same relevant facts present here as to BSC's PROMUS stent. (*See* Declaration of Todd Messal ("Messal Decl.") at ¶¶ 12-14 and Exhibit A thereto (copy of the Court's July 27, 2007 Order)).

In separately-filed, pending actions in the District of New Jersey, Cordis has accused Abbott Laboratories' ("Abbott's") XIENCE V everolimus-eluting stent of infringing the Cordis patents and is seeking a permanent injunction against Abbott's making that stent in the United States. PROMUS is a private-labeled version of the XIENCE V stent that Abbott manufactures in the United States for BSC, pursuant to an agreement with BSC that requires Abbott to do so. Abbott is the only manufacturer of the PROMUS stent. (*See* C.A. No. 07-333, D.I. 1 at ¶¶ 17-21, "07-333 Compl."; C.A. No. 07-348, D.I. 1 at ¶¶ 17-21, "07-348 Compl."; C.A. No. 07-409, D.I. 1 at ¶¶ 17-21, "07-409 Compl."; collectively "BSC Complaints"; Messal Decl. at ¶¶ 6-7). Thus, Cordis presently is seeking to put BSC out of the business of selling its PROMUS stent. That certainly constitutes an injury to BSC that is sufficiently immediate and real to support standing.² (*See* 07-333 Compl. at ¶ 22; 07-348 Compl. at ¶ 22; 07-409 Compl. at ¶ 22).

² Notwithstanding their relationship concerning PROMUS, BSC and Abbott are major competitors in the medical device market, particularly as to stents. (*See* Messal Decl. at ¶¶ 9-11). BSC should not have to rely on a major competitor to defend against the Cordis patents. (continued...)

Cordis ignores the foregoing controversy, which is plainly set forth in BSC's complaints. *See id.* Instead, Cordis erroneously focuses solely on whether BSC has committed any act that could be accused of directly infringing the Cordis patents or will do so imminently, wrongly concludes that no such act has occurred (or will occur imminently), and then urges dismissal of BSC's complaints on that basis alone. (*See* Opening Brief at, *e.g.*, 1-2).

First, Cordis's narrow analysis was never the test of standing, and certainly is not following the *MedImmune* decision. Second, even if, *arguendo*, Cordis's narrow test were the law, BSC's complaints still would pass muster for standing. Abbott makes the PROMUS stent at BSC's request, pursuant to the requirements of an existing agreement with BSC. (*See* 07-333 Compl. at ¶¶ 17; 07-348 Compl. at ¶¶ 17; 07-409 Compl. at ¶¶ 17; Messal Decl. at ¶¶ 6-7). Therefore, BSC seeks a declaration in its complaints that it does not induce direct infringement (*e.g.*, by Abbott's making of PROMUS) under 35 U.S.C. § 271(b). (*See* BSC Complaints at Prayer for Relief, ¶ (b)). Third, BSC inspects and maintains the PROMUS stents in Massachusetts and readies them for transfer and sale in Europe. Finally, BSC will begin selling the PROMUS stent in the U.S., following FDA approval, which should occur in the first or second quarter of 2008. (*See* 07-333 Compl. at ¶¶ 18; 07-348 Compl. at ¶¶ 18; 07-409 Compl. at ¶¶ 18; Messal Decl. at ¶¶ 8).

There simply is no basis for dismissing the BSC actions. Therefore, this Court should find, as the Northern District of California recently did, that BSC has standing.

Under these circumstances, BSC should have its own opportunity to raise its own non-infringement and invalidity defenses against the Cordis patents, so that it can ensure that its vital business interests are fully protected.

STATEMENT OF RELEVANT FACTS

BSC is a world renowned leader in the development of intravascular stents used in the treatment of coronary artery disease. (See 07-333 Compl. ¶ 14; 07-348 Compl. ¶ 14; 07-409 Compl. ¶ 14). In April 2006, BSC acquired the cardiac rhythm management business of Guidant Corporation (“Guidant”) for \$27.2 billion. Prior to that acquisition, Abbott purchased Guidant’s vascular businesses, including its coronary stents, for \$4.1 billion in cash and other considerations. (See 07-333 Compl. ¶ 19; 07-348 Compl. ¶ 19; 07-409 Compl. ¶¶ 19; Messal Decl. at ¶¶ 3-5). Abbott’s XIENCE V stent, which Cordis has accused of infringing the Cordis patents, was originally developed by Guidant. (See Messal Decl. at ¶ 5). As part of the foregoing two deals with Guidant, BSC and Abbott entered into a separate agreement that requires Abbott to manufacture for BSC a private-label version of the XIENCE V stent. BSC sells this private-label stent under the designation “PROMUS,” and BSC has made a substantial investment in the PROMUS stent. (See 07-333 Compl. ¶¶ 18-20; 07-348 Compl. ¶¶ 18-20; 07-409 Compl. ¶¶ 18-20 and Messal Decl. at ¶¶ 6-8).

BSC has been selling the PROMUS stent in Europe since January of 2007. (See 07-333 Compl. ¶ 18; 07-348 Compl. ¶ 18; 07-409 Compl. ¶ 18; Messal Decl. at ¶ 8). BSC takes possession of the PROMUS stents from Abbott in Temecula, California and ships them to its facility in Massachusetts. There, BSC inspects and maintains the stents, and then readies them for transfer and sale in Europe. (See *id.*). An FDA application has been made for the PROMUS stent, and BSC plans to commercially launch that stent in the United States in the first or second quarter of 2008. (See 07-333 Compl. ¶ 18; 07-348 Compl. ¶¶ 18; 07-409 Compl. ¶¶ 18; Messal Decl. at ¶ 11). BSC, Cordis, and Abbott are all competitors in the medical device market, as BSC makes and sells several other stent products in the United States and worldwide, including the

Taxus drug-eluting stent. Abbott markets its XIENCE V stent as an alternative to Taxus. (*See* 07-333 Compl. ¶¶ 14-16; 07-348 Compl. ¶¶ 14-16; 07-409 Compl. ¶¶ 14-16; Messal Decl. at ¶¶ 9-11).

This case is only one part of a much larger dispute that separately pits BSC and Abbott against Cordis, and comprises multiple cases pending before this Court, involves multiple Cordis patents, and is centered on the same, everolimus-eluting stents (BSC's PROMUS stent and Abbott's XIENCE V stent). There are now a total of *five* such related cases against Cordis before this Court, three filed by BSC and two filed by Abbott.³ (*See* 07-409 Compl. ¶¶ 23-32). Cordis has not answered the complaints in either of the two Abbott litigations related to BSC's three complaints. Cordis moved to dismiss the first of the two Abbott litigations (C.A. No. 06-613-SLR) for alleged lack of subject matter jurisdiction. In the other one (C.A. No. 07-259-SLR), Abbott moved to enjoin Cordis from pursuing its later-filed cases in the District of New Jersey (which involve the Falotico '286 patent and the Wright '286 patent). Cordis responded by arguing that Abbott's May 15 declaratory judgment action on the Falotico '286 patent should be transferred to the District of New Jersey.

In ruling on a BSC motion to intervene, another Federal District Court has already found

³ These five related cases before this Court are: (1) Abbott's September 29, 2006 declaratory judgment action against Cordis (C.A. No. 06-613-SLR), alleging that Cordis's U.S. Patent Nos. 6,585,764, 6,776,796, and 6,808,536 are invalid and not infringed by Abbott's XIENCE V stent; (2) Abbott's May 15, 2007 declaratory judgment action (C.A. No. 07-259-SLR) alleging that Cordis's Falotico '286 patent is invalid and not infringed by the XIENCE V stent; (3) BSC's May 25, 2007 complaint alleging that the Falotico '286 patent is invalid and not infringed by the PROMUS stent (C.A. No. 07-333-SLR); (4) BSC's June 1, 2007 action alleging that Cordis's Wright '286 patent is invalid and not infringed by the PROMUS stent (C.A. No. 07-348-SLR); and (5) BSC's June 22, 2007 action against Cordis, alleging that Cordis's Wright '473 patent is invalid and not infringed by the PROMUS stent (C.A. No. 07-409-SLR). In addition, in its Civil Action No. 06-613-SLR, Abbot has filed a motion for leave and two supplements to add the Falotico '286 patent, the Wright '286 patent, and the Wright '473 patent to that case.

that BSC has standing under the *MedImmune* test in view of the same relevant facts present here regarding the PROMUS stent. That patent infringement case, styled *Medtronic Vascular et al. v. Advanced Cardiovascular Systems, Inc. et al.*, C.A. No. 06-01066-PJH (N.D. Cal.), includes allegations that Abbott's XIENCE V stent infringes two different patents than those at issue here. (See Messal Decl. at ¶¶ 12-14 and Exhibit A thereto).

ARGUMENT

Cordis's motion to dismiss fails on multiple grounds and should be rejected by this Court. Cordis: (1) argues for dismissal based on an overly-narrow view of the standing test; (2) ignores the relationship between Abbott, BSC, and their respective XIENCE V and PROMUS stents which, coupled with Cordis's infringement actions against Abbott, created the controversy that provides subject matter jurisdiction in BSC's three complaints; and (3) wrongly concludes that BSC's complaints should be dismissed under its overly-narrow view of standing.

I. BSC Satisfies the Proper Legal Standard for Declaratory Judgment Jurisdiction

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a). BSC's complaints fully meet this standard and should not be dismissed.

A. Cordis Applies an Overly-Narrow "Test" for Standing

The Supreme Court recently held that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (quoting *Md. Cas. Co. v. Pac. Coal &*

Oil Co., 312 U.S. 270, 273 (1941)). Thus, the Supreme Court found that there is no longer a requirement that a declaratory judgment plaintiff show a reasonable apprehension of suit. *See id.* Here, both the new, “substantial controversy” standard of *MedImmune* and the past “reasonable apprehension of suit” standards are met; BSC absolutely is in apprehension of suit on the PROMUS stent given Cordis’s express infringement allegations against Abbott’s same stent.

Notwithstanding that Cordis cites the *MedImmune* case in its brief, it ignores the full breadth of its holding. Cordis instead narrows the test of subject matter jurisdiction to require that: (1) BSC already has committed an act that could be accused of direct infringement of the Cordis patents; or (2) that such an act by BSC is imminent. According to Cordis, no such act has occurred (or is imminent), therefore it has not sued BSC for infringement (in contrast to its pending infringement cases against Abbott on the XIENCE V stent), and BSC should not be permitted to bring its declaratory judgment complaints at this time. However, the law of standing is not so narrow as Cordis urges.

Indeed, in further explaining the Supreme Court’s holding in *MedImmune*, the Federal Circuit held that “a declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under ‘all the circumstances’ an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of ‘sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’” *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1338 (Fed. Cir. 2007) (quoting *MedImmune*, 127 S. Ct. at 771); *see also Sandisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1378-80 (Fed. Cir. 2007). Such a plaintiff must “‘allege personal injury fairly traceable to the defendant’s allegedly unlawful conduct and likely to be redressed by the requested relief.’” *Teva*, 482 F.3d at 1337 (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)).

The Federal Circuit further noted that among the standing requirements, the most determinative is injury-in-fact. *Id.* Specifically, the injury-in-fact must be “personal,” “concrete and particularized,” and “actual or imminent.” *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). As for the ripeness requirement the Federal Circuit noted that “[a] ‘controversy’ is ‘ripe’ if the question presented is ‘fit for judicial review,’ meaning it is entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party.” *Id.* (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149-50 (1967)).

Cordis’s motion fails chiefly because it ignores “all the circumstances” surrounding the relationship between BSC, Abbott and their respective stents, and focuses narrowly only on some circumstances, such as whether BSC has committed any act that could be accused of direct infringement, which is not the proper test of standing.

B. BSC’s Complaints Fully Satisfy the Proper Test for Standing

When one examines “all the circumstances” in this case, there is no doubt that BSC has standing to bring its complaints. BSC has alleged an injury-in-fact, the issue is ripe, real and immediate, and an “actual controversy” exists between BSC and Cordis.

Cordis has expressly accused an Abbott stent (XIENCE V) that is identical to BSC’s PROMUS stent of infringing the three Cordis patents at issue in BSC’s complaints. Cordis is seeking to permanently enjoin Abbott from making that stent. Abbott is the only manufacturer of the PROMUS stent, and only BSC can commercialize that stent. (*See* 07-333 Compl. ¶¶ 17-21; 07-348 Compl. ¶¶ 17-21; 07-409 Compl. ¶¶ 17-21; Messal Decl. at ¶¶ 6-8).

BSC has been selling the PROMUS stent in Europe since January of 2007, and expects to begin selling it in the United States in the first or second quarter of 2008. The PROMUS stent is an important part of BSC’s vascular business. BSC has invested heavily in that stent. Indeed,

Abbott is required to make that stent for BSC pursuant to an agreement that resulted from BSC's acquisition of Guidant for \$27.2 billion. Abbott's agreement to make the PROMUS stent and supply it to BSC was a key term of Guidant's sale of its vascular business to Abbott. (See 07-333 Compl. ¶¶ 18-19; 07-348 Compl. ¶¶ 18-19; 07-409 Compl. ¶¶ 18-19; Messal Decl. at ¶¶ 4-8).

Thus, Cordis is presently and actively pursuing a course of action to put BSC out of a very important part of its business, the marketing and selling of its PROMUS stent. That is a plain "injury-in-fact" to BSC. If Abbott, the sole manufacturer of that stent, is enjoined as a result of Cordis's actions, BSC would have no source of supply for that stent. It could no longer sell the PROMUS stent in Europe, as it has since January of 2007, or in the United States in early to mid-2008. Plainly, then, there exists here a "definite and concrete" dispute between BSC and Cordis that "touch[es] the legal relations of parties having adverse legal interests." *MedImmune*, 127 S. Ct. at 771. This is true even though Cordis states it has not sued BSC yet since BSC purportedly has not committed any act that could be accused of direct infringement. See *Sandisk*, 480 F.3d at 1382-83 (Fed. Cir. 2007) (finding that subject matter jurisdiction where the patentee "engaged in a course of conduct that shows preparedness and willingness to enforce its patent rights," notwithstanding patentees' statement that it had "absolutely no plan whatsoever" to file a lawsuit).

Further, BSC and Abbott are major competitors in the stent market. (See Messal Decl. at ¶¶ 9-11). BSC should not have to rely on a major competitor to defend against the Cordis patents. BSC should have its own, independent opportunity to raise non-infringement and invalidity defenses against the Cordis patents, so that it can ensure that its vital business interests are fully protected.

Under “all the circumstances” identified above, there is an actual or imminent injury caused by Cordis that can be redressed by judicial relief and that is of “sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Teva*, 482 F.3d at 1338 (quoting *MedImmune*, 127 S. Ct. at 771); *see also Sandisk*, 480 F.3d at 1382-83. BSC should not be forced to wait and see whether Cordis can put it out of the PROMUS stent business.

C. The Northern District of California Recently Found that BSC Had Standing in a Case With the Same Relevant Facts

Abbott is a defendant in a patent infringement case in the Northern District of California, styled *Medtronic Vascular et al. v. Advanced Cardiovascular Systems, Inc. et al.*, C.A. No. 06-01066-PJH, which includes allegations that Abbott’s XIENCE V stent infringes two patents and seeks to enjoin Abbott from making that stent. BSC moved to intervene in that California case because it was in fear of being sued on the same two patents-in-suit on its PROMUS stent. BSC wanted to protect its vital business interests in the PROMUS stent by joining the case, which also would preserve judicial resources by resolving the related issues among BSC, Abbott and the plaintiffs in one case. On July 27, 2007, the Court in the California case granted BSC’s motion to intervene. (*See* Messal Decl. at ¶¶ 12-14). In doing so, the Court found that, if standing were a requirement to intervene as of right (which was disputed by the parties in the briefing), BSC had established such standing under the test recently enunciated by the Supreme Court in *MedImmune* because, *inter alia*, “FDA approval is expected in early or mid-2008, Abbott is already manufacturing that [PROMUS] stent for BSC in the United States, BSC is already selling that stent in Europe, and plaintiffs have accused that stent in this patent infringement action.” (*See id.* and Exhibit A thereto at 2).

The relevant facts are the same here as in the above case in the Northern District of California.⁴ This Court likewise should find standing and reject Cordis's motions to dismiss.

II. BSC's Complaints Also Satisfy Cordis's Overly-Narrow "Test" for Standing

A. Cordis Has Accused the Same Stent that Abbott Makes for BSC of Infringing the Cordis Patents at Issue in BSC's Complaints

BSC's complaints also meet the overly-narrow (and now-rejected by the Supreme Court in *MedImmune*) "test" for standing presented in Cordis's Opening Brief. One way (but not the only way) that a declaratory judgment plaintiff may establish the existence of an injury-in-fact is by alleging that it is performing acts that could constitute infringement of the patent-in-suit. *See, e.g., MedImmune*, 127 S. Ct. at 767-68; *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1481-82 (Fed. Cir. 1998). BSC's complaints fully allege just such an injury-in-fact.

35 U.S.C. § 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To be liable for inducement of infringement the patentee must show "that there has been direct infringement" and "that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minn. Mining & Mfg. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). Here, Cordis expressly has accused Abbott's XIENCE V stent of directly infringing the Cordis patents at issue in BSC's complaints. Pursuant to an agreement with BSC resulting from the Guidant acquisition, Abbott is required to (and does) manufacture the same stent in the United States for BSC, which BSC sells under a different name (PROMUS). (*See* 07-333 Compl. ¶¶ 17-21; 07-348 Compl. ¶¶ 17-21; 07-409 Compl. ¶¶ 17-21; Messal Decl. at ¶¶ 6-7). BSC's complaints set forth those facts

⁴ Although Cordis has not expressly accused the PROMUS stent of infringement in the co-pending Abbott litigations, as was the case by the plaintiff in the *Medtronic* case, the effect is exactly the same since Cordis has accused the same stent as PROMUS (Abbott's XIENCE V) of infringement and is seeking to enjoin Abbott from making such stents, which would put BSC out of the business of selling its PROMUS stents.

and, accordingly, seek a declaration that BSC is not liable for inducing infringement of the Cordis patents (*e.g.*, due to the agreement that requires Abbott to manufacture the PROMUS stent for BSC). (*See* BSC Complaints at Prayer for Relief, ¶ (b)). That alone is enough to establish subject matter jurisdiction and warrant denial of Cordis's motions to dismiss. Indeed, actions that could be accused of inducing direct infringement alone are sufficient to provide declaratory judgment jurisdiction. *See Fina Research*, 141 F.3d at 1486.⁵

B. BSC Has the Immediate Intention of Selling the PROMUS Stent in the U.S.

Under the pre-*MedImmune* case law, subject matter jurisdiction was found where the “[p]laintiff . . . made meaningful preparation for such activity [that could be accused of infringement].” *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). BSC's complaints also meet this “meaningful preparation” or “imminent act” standard that Cordis proffers as the alternative prong of its overly-narrow “test” of standing.

BSC's complaints allege facts that show that BSC has made meaningful preparation to offer for sale and sell the PROMUS stent in the United States in 2008. BSC has and continues to invest substantial resources in the PROMUS stent for its expected launch in the United States early next year. An FDA filing has been made for the PROMUS stent, and BSC expects to begin selling the PROMUS stent in the United States in the first or second quarter of 2008. (*See* 07-333 Compl. ¶¶ 17-20; 07-348 Compl. ¶¶ 17-20; 07-409 Compl. ¶¶ 17-20; Messal Decl. at ¶¶ 3, 8, 11). Thus, by any definition, BSC plans to launch the PROMUS stent in the United States “imminently,” and that alone should establish subject matter jurisdiction over BSC's complaints.

⁵ Nor is it sufficient to say that BSC should wait to see whether Abbott is found liable for direct infringement in its actions against Cordis. Again, notwithstanding that Abbott presently makes the PROMUS stent for BSC, Abbott and BSC are competitors in the stent arena. BSC has suffered its own injury from Cordis's actions and deserves its own redress against the Cordis patents.

Indeed, the Northern District of California recently cited BSC's scheduled plan to launch the PROMUS stent in the United States as a factor in finding that BSC had standing under the *MedImmune* test, in a case with the same relevant facts as here. (See Messal Decl. at ¶¶ 12-14 and Exhibit A thereto).

The cases cited by Cordis that address the issue of immediacy are inapposite to the present litigation. As an initial matter, all of the cases cited by Cordis involve the situation where the declaratory judgment plaintiff is the patentee who seeks a declaratory judgment that the defendant infringes a particular patent. See *Lang v. Pacific Marine & Supply Co., Ltd.*, 895 F.2d 761 (Fed. Cir. 1990); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992); *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590-GMS, 2006 WL 2375035 (D. Del. Aug. 16, 2006); *AlphaMed Pharms. Corp. v. Arriva Pharms., Inc.*, 391 F. Supp. 2d 1148 (S.D. Fla. 2005); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995). It is not surprising that courts in these cases are more hesitant to allow a patentee to seek a declaratory judgment that a party may, in the future, infringe a patent, especially when the patentee has little to lose if the suit is initiated at a later point in time.

More specifically, *Lang* is inapposite because the court noted that the accused infringer had not "engaged in any activity indicating that the [accused infringing] ship would soon be ready for sea." *Lang*, 895 F.2d at 765. Conversely, BSC's PROMUS stent is being manufactured by Abbott in the U.S. for BSC, it is presently on sale in Europe and it is expected to be on sale in the U.S. in early to mid-2008.

Telectronics is inappropriately relied upon because the accused infringer was "years away" from obtaining FDA approval and the accused product was actually modified during

clinical testing. *Telectronics*, 982 F.2d at 1527. *Abbott Diabetes Care* is inapposite because the court noted that there was no showing that the accused infringer “produced or has prepared to produce a product that would be subject to an infringement charge.” *Abbott Diabetes Care*, 2006 WL 2375035, at *3. *AlphaMed* is inapposite because the court noted that the plaintiff “has not identified an infringing product,” “has not alleged that [the accused infringer] has sought FDA approval for any particular drug,” and “has not even alleged that [the accused infringer] has developed any drug that *could* gain FDA approval.” *AlphaMed*, 391 F. Supp. 2d at 1158 (emphasis in original). Furthermore, the court noted that the accused infringers activities were protected by 35 U.S.C. § 271(e)(1). *Id.* at 1160.⁶

Cordis tries in vain to distinguish the present case from *Abbott Labs. v. Baxter Healthcare Corp.*, No. 04-C-836, 2004 WL 1878291 (N.D. Ill. Aug. 16, 2004), arguing that the accused infringer there had already received FDA approval for its product which warranted the finding of standing to sue. (Opening Brief at 9 n.5). The *Baxter* holding, however, says and does nothing to rule out declaratory judgment jurisdiction when the accused infringer has not yet received FDA approval. Indeed, the *Baxter* Court cited to *Glaxo Group Ltd v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008-09 (N.D. Ill. 2001), in which the court held that declaratory judgment jurisdiction was proper even though the accused infringer had not yet received FDA approval but had engaged in meaningful preparation directed toward making, selling, or using the product.

⁶ Likewise, the *Amgen* case is inapposite since the court declined to exercise declaratory judgment jurisdiction when the plaintiff is the patentee because “subjecting the [accused infringers] to an infringement litigation [before FDA approval] may run afoul of the Congressional policy underlying the § 271(e)(1) exemption.” *Amgen*, 3 F. Supp. 2d at 112. *Zenith Laboratories* also is inapposite because the court noted that the plaintiff-patentee did not allege facts “sufficient to show that [the accused infringer] intends to enter the market.” *Zenith Labs.*, 934 F. Supp. at 938. Furthermore, the court noted that to allow the case to proceed would undermine Congress’ intent in passing § 271(e)(1). *Id.*

Cordis also argues that *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) is distinguishable from the present case (Opening Brief at 9 n.5). Cordis is wrong. In *Novopharm*, as here, the accused infringer “was not ‘years away’ nor was there doubt that [it] wished to sell some form of [the accused product]. Rather, [the accused infringer] was systematically attempting to meet the applicable regulatory requirements while preparing to import its product.” *Novopharm*, 110 F.3d at 1571 (internal citation omitted). Thus, the court there held that declaratory judgment jurisdiction was proper. *Id.*

III. This Court Should Not “Decline to Hear the Case,” as Cordis Urges; Rather, this Court Should Hear this Case and Abbott’s Related Cases Together

Cordis argues that this Court should decline to exercise its jurisdiction even though BSC’s allegations are sufficient to meet the “actual controversy” requirement of the Declaratory Judgment Act. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813 (Fed. Cir. 1996). However, in deciding whether to decline to exercise jurisdiction “[i]t is appropriate . . . for a district court to examine whether hearing the declaratory judgment action would serve the objectives for which the Declaratory Judgment Act was created.” *Id.* at 814.

Here, there is no doubt that the objectives for which the Declaratory Judgment Act was created manifestly would be served by hearing BSC’s complaints. There is an indisputably real, immediate, ripe, and present controversy between BSC and Cordis, which have adverse legal interests. BSC is entitled to a resolution of the controversy recited in its complaints. BSC should not have to sit and wait on the sidelines while Cordis is trying to put it out of the business of selling the PROMUS stent.

Moreover, the present controversy is significantly intertwined with Abbott’s pending declaratory judgment actions in this Court against Cordis, which involve the same Cordis patents and the same stent, which Abbott makes and sells under a different name. Cordis has been and is

actively trying to dismiss and/or transfer the Abbott litigations from this Court. Now it has turned its dismissal efforts against BSC's complaints. Neither BSC's nor Abbott's complaints should be dismissed or transferred from this Court, however. These related cases involve the same Cordis patents and the same stents and should be heard together, in this forum.⁷

CONCLUSION

For all of the foregoing reasons, the Court should deny Cordis's motions to dismiss BSC's complaints for lack of subject matter jurisdiction.

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Dated: August 13, 2007

⁷ As noted above, if the Court finds that it would be more efficient, BSC is amenable to having its complaints consolidated with Abbott's pending action on the Cordis patents.

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on August 13, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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